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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/889,383 | 02/05/2002 | Marco Thyges | 0480-01211 | 2952 |
| 26474 | 7590 | 11/16/2004 | EXAMINER | |
| KEIL & WEINKAUF 1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036 | | | OH, TAYLOR V | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,383

Applicant(s)

THYES ET AL.

Examiner

Taylor Victor Oh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Final Rejection

The Status of Claims

Claims 1-2 are pending.

Claims 1-2 have been rejected.

Claim Rejections-35 USC 103

1. Applicants' argument filed 8/23/04 have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

***Rejection of Claims 1-2 under 35 U.S.C. 103(a) as being unpatentable over
Warner Lambert Pharmaceutical Co.(GB 1226318).***

The rejection of Claims 1-2 under 35 U.S.C. 103(a) as being unpatentable over Warner Lambert Pharmaceutical Co.(GB 1226318) is maintained for the reasons of the record on 5/26/04.

Applicants' Argument

2. Applicants argue the following issues:
 1. There is no motivation in the prior art to modify the Warner Lambert Pharmaceutical Co reference to achieve the current invention;
 2. The use of a greater amount of acid in the prior art is disadvantageous since it has no purpose and it is less economical ; furthermore, it can not be obvious to use the claimed amounts of 0.75 : 2 (acid: isomeric mixture);
 3. According to the prior art , it seems logical to make the reaction time from 5 to 20 min to be as short as possible unlike the claimed reaction time which is from 0.5 to 2 hours ;therefore, it cannot be obvious to the prior art to keep the reaction time to be longer than necessary.

The applicants' argument have been noted, but these arguments are not persuasive. First, with respect to the first argument, the Examiner has noted applicants' argument. However, that the prior art does teach that the content of ethyl 3-dimethylamino-2-phenylpropionate present in the final product (a trans form of ethyl 2 – dimethylamino-1-phenyl-3-cyclohexene-1-carboxylate) is less than 0.25 % in the mixture (see col. 4, lines 69-70). Furthermore, applicants have acknowledged in the amendment that “it was known in the art to be desirable to reduce the content of 3-dimethylamino-phenyl-propionic acid-ethylester to about 0.1 %”. Therefore, it is clear that there is a motivation in the prior art. Thus, it would have been obvious to the skilled

artisan in the art to have motivated to reduce its content of impurity further to a less than 0.1 % in order for the desired final product to be used as a safe analgesic drug.

Second, with respect to the second argument, the Examiner has noted applicants' argument. However, the separation procedure in the prior art, a ratio of from 1 to 1.2 mol of oxalic acid or fumaric acid per each mol of trans-isomer is present in the isomeric mixture (see col. 2, lines 99-102). Also, in the claim 1 of the current invention, the limitation of "adding from 0.75 to 2.0 equivalents of a carboxylic acid per mole of ethyl 2 -dimethylamino-1-phenyl-3-cyclohexene-1-carboxylate to this solution" is described. By comparison, the prior art and the current invention with respect to the ratio between the acid and ethyl 2 -dimethylamino-1-phenyl-3-cyclohexene-1-carboxylate are overlapped with each other. Therefore, applicants' argument is irrelevant to the issues of the invention.

Third, with respect to the third argument, the Examiner has noted applicants' argument. However, Warner Lambert Pharmaceutical Co reference does indicate that the reaction time can be in the range of from 5 to about 20 mins or a longer (see col. 2, lines 61-64), whereas the current invention is from 0.5 to 2 hours. The claimed ranges and the prior art ranges do not overlap but are close enough that one skilled artisan in the art would have expected them to be in the similar reaction condition in the absence of an unexpected result. Furthermore, the limitation of a process with respect to ranges of pH, time and temperature does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum

operation of the process. Reaction time is well understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control selectivity in a chemical process. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to modify the prior art reaction time to the claimed one by routine experimentation in order to control the selectivity of the desired product. This is because the skilled artisan in the art would expect such a modification to be successful and to be selective for the desired product.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Taylor Victor Oh
11/14/04

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